IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 1 CASES LISTED IN EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF TIMOTHY BRIAN MCKINNEY, M.D.

COME NOW Ethicon Wave 1 Plaintiffs listed in Exhibit A and file this Memorandum in Support of Plaintiffs' Motion to preclude Timothy Brian McKinney, M.D., a proffered general expert witness for the Defendants, from giving any opinions, including opinions regarding the design, use and/or safety of Defendants' Prolene Soft (Gynemesh PS) ("Prolene mesh") pursuant to Federal Rule of Evidence 701 and *Daubert v. Merrell Dow Pharms*., 509 U.S. 579, 592 (1993).

INTRODUCTION

Dr. McKinney's opinions fail on all aspects of the *Daubert* inquiry. Dr. McKinney's deposition testimony reveals that he relied solely on his "personal experience" in formulating his opinions, unsupported by any peer reviewed scientific or medical sources. Moreover, Dr. McKinney's own "publications" have not been published in generally accepted medical journals, and have not otherwise been subject to peer review. Against this backdrop, Dr. McKinney admitted in his deposition that his opinions are based on information and data selectively provided to him by Defendants' counsel. He failed to take into account – or could not explain –

conflicting medical studies and reports, including several reports by the Food and Drug administration. This Court has repeatedly affirmed that the *Daubert* test employs a number of factors designed to assess the "principles and methodology" of an expert – not his conclusions. The record in this case demonstrates numerous and significant failures in Dr. McKinney's methodology, which on their face render his opinions purely anecdotal and unable to withstand critical scrutiny regarding their reliability.

SUMMARY OF DR. MCKINNEY'S PROPOSED EXPERT TESTIMONY

1. Defendants' Designation of Dr. McKinney as a General Expert.

On March 2, 2016, Defendants served their "Identification of Experts Pursuant to PTO # 205" in each of Plaintiffs' cases. (See Exhibits "B" and "C").

According to Defendants' identification, Dr. McKinney, a urogynecologist, is designated to testify as a general expert. (*Id.*).

2. Dr. McKinney's Opinions Contained in His Expert Report.

Defendants also served on March 2, 2016 a copy of Dr. McKinney's general expert report regarding "Prolene Soft (Gynemesh PS)". (Exhibit "D", McKinney Report).

a. Publications and Qualifications.

Dr. McKinney states in his report that his qualifications include his education and teaching experience at Drexel University College of Medicine in Philadelphia, Pennsylvania. (Report at p. 2).

In addition to his education, Dr. McKinney then offers as his qualifications a number of "abstracts", "monographs", and other materials he wrote. Dr. McKinney then states that "[i]n addition to my public literature, when I was practicing full time my website had a discussion about vaginal repair with mesh, publications of the IUGA findings and a commentary on the

FDA safety communication released in July, 2011 all to educate my patients and other doctors better." (*Id.* at pp. 2-3).

Finally, Dr. McKinney states that "[i]n January, 2013 my partner and I were chosen as one of the few sites to participate by AMS in their post-marketing studies". (*Id.* at p. 3).[1]

b. Opinions Regarding the Safety and Efficacy of Prolene Mesh.

Dr. McKinney in his Report states that "[s]everal studies demonstrate the versatility of Prolene Soft mesh, describing its use in various gynecologic procedures other than transvaginal procedures." (*Id.* at p. 10). He then over the next several pages reports the findings of a number of studies ranging from 2001 through 2013. (*Id.* at pp. 10-14).

Dr. McKinney then states that "[o]ngoing technological advances of synthetic meshes using polypropylene have been a moving target, with development of lighter and less stiff materials over the last 10 years. At the time of introduction of Gynemesh PS in the early 2000s, the material was considered the least stiff and most porous mesh to receive FDA clearance and introduction into the surgical market. The stiffness, weight, and porosity of Gynemesh PS has subsequently moved to the middle of the spectrum of synthetic mesh products as recent science has favored the least stiff, lightest weight, and most porous material possible." (*Id.* at p. 15).

Dr. McKinney concludes by stating that "[t]he theory of mesh degradation is not substantiated in the literature or in my personal experience using polypropylene slings and mesh for incontinence treatment and pelvic reconstruction. Studies of explanted mesh are difficult to interpret". (*Id.* at p. 17). He also gives the conclusory opinion that "[t]he literature also refutes plaintiffs' experts' suggestion or claim." (*Id.*).

[1] Dr. McKinney's current professional situation is unclear. He testified at his deposition that while he still holds a faculty position at Drexel University, he had to close his private practice for "financial reasons" and is in the process of "reorganizing" himself. (Exhibit "E" at 15:17-24).

3. Dr. McKinney's Deposition Testimony.

Dr. McKinney's deposition was taken on April 14, 2016. (Exhibit "E"). His testimony revealed that his opinions were based on his anecdotal "personal experience" and that the medical and scientific data he reviewed was selectively provided to him by Defendants' counsel. His testimony also shows that he failed to take into consideration conflicting studies, and could not account for those studies. Finally, he testified that his own "publications" have not been subject to peer review.

a. Dr. McKinney's "Publications" Not Subject to Peer Review.

Despite vaguely referring to numerous "publications" in his report, Dr. McKinney admitted in his deposition that nothing he has written has been subject to peer review:

Q. Have you published articles on polypropylene mesh?

A. Yes, I have.

Q. And can you share with us how many are published in peer-reviewed publications?

A: None.

(Exhibit "E" at 47:20-48:1).

Dr. McKinney later in his deposition confirmed that none of his "abstracts" were published in peer review literature. (*Id.* at 121:2-4).

b. Information Selectively Provided by Counsel.

Dr. McKinney's testimony that his opinions are based solely on his own personal experience is confirmed by his admission that he did not do any of his own, independent research in connection with his testimony. Rather, he testified that any materials he had were provided to him by Defendants' counsel:

Q. The articles that are referenced in your expert report and/or in your reliance list, did you obtain those articles -- did you obtain the titles of those articles on your own during any research, or were these provided to you by anyone?

A. A lot of them were provided to me from counsel.

Q. Okay. But did you do your own PubMed research at any point?

A. I did not. (*Id.* at 13:11-20).

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Q. In any search that you may have done yourself in preparation for developing your opinions and/or writing your report, did you conduct PubMed search using, for example, the terms polypropylene mesh -- well, let's just stick with that, polypropylene mesh?

A. I did not. (*Id.* at 47:5-11). *See also Id.* at 65:23–66:1; 69:13-23.

c. Failure to Account for Conflicting Studies and FDA Advisories.

Dr. McKinney in his report failed to acknowledge any studies and reports which conflict with his own opinions:

Q. In your expert report where you write polypropylene is inert, do you mention that there are contrary opinions in the peer-reviewed published literature?

A. I do not. (*Id.* at 62:8-12). *See also Id.* at 63:13-15.

In fact, when questioned about his conclusion that mesh does not contract, Dr. McKinney admitted that he had not read or considered a number of peer review articles which found that it did contract. (*Id.* at 94:4-96:1). Instead, Dr. McKinney simply countered that he relied on his own personal experience. (*Id.* at 95:23-24). Dr. McKinney had the same response – that his "personal experience" supplanted peer reviewed studies – when questioned about a number of other articles which contradicted his conclusions. (*Id.* at 102:9-103:13).

Dr. McKinney also failed to taken into account in his report that the FDA changed its guidance between 2008 and 2011 from "serious complications are rare" to "serious complications are not rare", which the FDA in fact bolded. (*Id.* at 35:13-18).

Similarly, Dr. McKinney in his report did not account for the FDA's advisory indicating that it is not clear that transvaginal pelvic organ prolapse ("POP") repair with mesh is more effective than traditional non-mesh repair in all patients with POP. Nor could Dr. McKinney explain that advisory. (*Id.* at 36:23-37:11).

In fact, many of Dr. McKinney's conclusions ***conflict*** with the FDA's advisories:

Q: [I]n your expert report, you refer to the mesh erosions as essentially a wound complication, do you not?

A. Like in other surgeries, yes.

Q. However, the FDA links mesh erosion as with some of the serious complications associated with the use of mesh, correct?

A. They are saying that.

Q. Do you consider mesh erosion into the vagina to be a serious complication?

A. Not necessarily. (*Id.* at 42:2-11).

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Q. You would agree that as of July 2011, the FDA indicating that the serious complications from mesh surgery exceeds those with the native tissue? . . .

THE WITNESS: There aren't any good studies that would equate that. (*Id.* at 44:6-11).

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Q. [Reading FDA Advisory]: Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the October 20th, 2008 FDA Public Health Notification. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain. Did I essentially read that correctly?

A. Yes.

Q. Now, this is the July 2011 safety update, but in your March 2016 expert report, you state your opinion that mesh does not contract; is that correct?

A. I do.

Q. And what is the objective basis for your belief that mesh does not contract?

A. I believe that the mesh is inert and it doesn't contract . . . (*Id.* at 44:18-45:12).

Dr. McKinney goes on to acknowledge that his conclusions conflict with a number of other scientific, medical and FDA publications, each time giving as the "objective" basis for his opinion his "personal experience. (E.g., *Id.* at 58:4-6; 59:3-5).

Dr. McKinney also acknowledges that he had not reviewed or cited any of the supporting studies cited by the FDA for its conclusions in its regulatory advisories. (*Id.* at pp. 83-91).

Dr. McKinney could not state any objective basis for disagreeing with the FDA's analysis, stating that he could "only comment from [his] own experience." (*Id.* at 91:15-92:5).

d. Dr. McKinney's Admitted Limited Timeframe for Proffered Opinions.

Dr. McKinney also admitted that his expertise – if any – is limited to the "early timeframe" of the Prolene mesh:

Q. I noticed in my review of your expert report in preparation for today that many, if not most of the articles, are dated in early 2000s and up to and including 2011 and 2012 and very few from 2015, 2016. Is there a reason for that?

A. Because I'm only an expert for the Gynemesh PS and Gynemesh doing the early portions as the expert for this product line. (*Id.* at 13:24 – 14:7).

Defendants in their designation of Dr. McKinney fail to place any such limitation on the scope of his testimony.

d. Opinions Based Solely on "Personal Experience" which Conflict with Scientific Studies.

Despite reciting a number of publications in his report (selected by Defendants' counsel), Dr. McKinney repeatedly acknowledged in his deposition that his opinions are based solely on his personal experience:

Q. Now, you started off your answer by saying I believe that the mesh is inert and my question is what objective basis are you relying upon for your opinion that mesh itself does not contract?

A. In that my own personal experience, as well as that mesh doesn't change its shape as such. (*Id.* at 45:22-46:3).

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Q. Now, there aren't any references for those opinions listed there, correct?

A. Correct.

Q. Can you give us objective evidence of what you're relying upon for your opinion that first the mesh does not shrink?

A. Just my personal experience with it that -- and from numerous communications and educational talks through -- from meetings, but mainly my personal experiences. (*Id.* at 51:5-14)

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Q. Is it fair to say that you do not opine upon those articles in your expert report as for evidence, in fact, of shrinkage and an inflammatory response?

A. That's correct. (*Id.* at 53:5-9).

Dr. McKinney bases his opinions solely on personal experience throughout his testimony, even when that "experience" conflicts with published peer review materials. He is unable to cite to specific peer reviewed material which support his "experience." (*Id.* at 76:22-77:9; 78:21-79:1).

ARGUMENT

Dr. McKinney's proposed expert testimony should be excluded for several independent reasons, both procedural and substantive. First, Dr. McKinney in his deposition repeatedly confirmed that his opinions are based solely on his own unexplained and unsubstantiated "personal experience". Not only has this Court rejected this type of "ipse dixit" expert testimony in the past, but its lack of reliability in this case is even more striking given that Dr. McKinney's "personal experience" directly conflicts with the finding of numerous peer reviewed and published findings. Dr. McKinney cannot explain this stark discrepancy.

Moreover, Dr. McKinney admits that the only materials he did review were selectively provided by Defendants' counsel. He further admitted that the materials related to early Prolene studies and findings, and that he was qualified to give opinions only as to "early timeframe".

Finally, Dr. McKinney acknowledges that there are numerous studies and reports which conflict with his opinions – including FDA advisories -- which he did not consider and which he cannot reconcile.

Each of these problems with Dr. McKinney's testimony has been cited by this and other courts as a reason for excluding an expert's opinions. Together, they demonstrate that Dr. McKinney's principles and methodology is fundamentally flawed and that his testimony is unreliable and should be excluded in its entirety.

I. Legal Standard for Determining Admissibility.

This Court set forth in *Edwards v. Ethicon, Inc*., 2014 U.S. Dist. LEXIS 92316 (S.D. W. Va. July 8, 2014), the standards which it has consistently applied in performing its "gatekeeper" function in analyzing the admissibility of expert opinion pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms*., 509 U.S. 579, 592 (1993) ("*Daubert*").

"A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Edwards* at *3, citing *Daubert* at 597. "The proponent of expert testimony does not have the burden to 'prove' anything. He must, however, 'come forward with evidence from which the court can determine that the proffered testimony is properly admissible.'" *Edwards* at *3-4, citing *Md. Cas. Co. v. Therm-O-Disc, Inc*., 137 F.3d 780, 783 (4th Cir. 1998).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an

expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

"*Daubert* mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include:

(1) whether the particular scientific theory 'can be (and has been) tested';

(2) whether the theory 'has been subjected to peer review and publication';

(3) the 'known or potential rate of error';

(4) the 'existence and maintenance of standards controlling the technique's operation'; and

(5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community." *Edwards*, *4, citing *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

"The inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Edwards* at *4, quoting *Daubert* at 594-95.

II. The Only Sources Cited by Dr. McKinney Were Selectively Provided By Defendants' Counsel.

As an initial matter, courts have routinely held that an expert's opinions lack reliability where the only materials reviewed were provided by counsel. See *Danley v. Bayer (In re Mirena IUD Prods. Liab. Litig.)*, 2016 U.S. Dist. LEXIS 29752, *91-92 (S.D.N.Y. Mar. 8, 2016) (only materials reviewed by expert were "a number of articles supplied to him by Plaintiffs' counsel, which [expert] subsequently copied and pasted into his expert report. . . . This is not the level of rigor an expert in the field would apply and does not pass muster under *Daubert*."), citing *Mancuso v. Consol. Edison Co. of N.Y.*, 967 F. Supp. 1437, 1443 (S.D.N.Y. 1997) (finding

expert unqualified because he relied on counsel to supply him with relevant scientific literature and "subsequently attempted, with dubious success, to qualify himself as [an expert] by a selective review of the relevant literature"); *Prohaska v. Safamor, S.N.C.*, 138 F. Supp. 2d 422, 437 (W.D.N.Y. 2001) (criticizing "litigation-driven expertise" where expert "relied upon the plaintiff's attorney to provide him with the relevant scientific literature").

This Court confronted a similar – and instructive -- issue in *Tyree v. Boston Sci. Corp*., 2014 U.S. Dist. LEXIS 148312 (S.D. W. Va. Oct. 17, 2014), excluding an expert's testimony where counsel had selectively provided the expert with pathology samples for the expert to review. "The plaintiffs do not explain how or why they chose these twenty-four reports for [the expert's] review, and without such an explanation, I have no way of assessing the potential rate of error or the presence of bias." Id. at *45. The Court noted that it had reached the same conclusion in other cases. Id. See also *Hall v. Boston Sci. Corp*., 2015 U.S. Dist. LEXIS 23980, *31 (S.D. W. Va. Feb. 27, 2015).

Dr. McKinney's testimony here is clear that the only materials he considered and which are cited in his report were provided to him by Defendants' counsel. (Exhibit "E" at 13:11-20). Indeed, Dr. McKinney affirmatively confirmed that he did not undertake to do any individual research or investigation in connection with his testimony. (Id. at 47:5-11; 65:23–66:1; 69:13-23).

In light of the one-sided, slanted "litigation style" preparation for his testimony, Dr. McKinney is more akin to an advocate than an expert. His testimony should be excluded.

III. Dr. McKinney Relies Solely on His "Personal Experience", Which Has Not Been Peer Reviewed.

Dr. McKinney also should be excluded from giving opinions because he relies solely on his "personal experience", which he admits has never been subject to peer review. Further, he

adheres to those opinions even in the face of numerous contradictory peer reviewed reports, which he cannot reconcile or explain.

This Court has repeatedly affirmed throughout this litigation that an expert "may not solely rely on his personal observations, especially when he seeks to provide broad opinions, such as the infection rate in women with mesh." *Frankum v. Boston Sci. Corp*., 2015 U.S. Dist. LEXIS 57251, *24 (S.D. W. Va. May 1, 2015), citing *Daubert v. Merrell Dow Pharms*., 509 U.S. 579, 592 (1993). Rather, "[p]roposed testimony must be supported by appropriate validation—i.e., 'good grounds,' based on what is known". Id., citing *Md. Cas. Co. v. Therm-O-Disk, Inc*., 137 F.3d 780, 783 (4th Cir. 1998) (internal citations omitted).

Based on these standards, the Court has repeatedly held that expert testimony is inadmissible where it is based solely on personal experience, unsupported by reliable medical or scientific data. See, e.g., *Sanchez, supra* at *42 (opinions based on personal experience alone, without scientific evidence or studies to support them, are inadmissible); *In re Ethicon, Inc*., 2014 U.S. Dist. LEXIS 15351, *2602 (S.D. W. Va. Jan. 15, 2014) (expert's "opinion is unreliable because it is merely *ipse dixit*, unsupported by any particular regulations or authorities."); *Tyree, supra* at 524 (testimony unreliable where expert could not cite to a supporting study), citing *Sanchez, supra*, at *17.

Nor may an expert obliquely reference unspecified "publications" which he claims support his views, as Dr. McKinney does in his deposition testimony. *Wise v. C. R. Bard, Inc*., 2015 U.S. Dist. LEXIS 14869, *25-26 (S.D. W. Va. Feb. 7, 2015) ("without a fully synthesized representation of [expert's] database, specific reliance on that database is unreliable").

As detailed above, Dr. McKinney consistently emphasizes throughout his testimony that his opinions are based solely on his personal experience rather than any of the wealth of peer

reviewed publications in this area. (See, e.g., Exhibit "E" at 51:5-14; 45:22-46:3 (personal experience is basis for opinion that mesh contracts). In fact, Dr. McKinney is unable to cite to specific peer reviewed material which support his "experience." (*Id.* at 76:22-77:9; 78:21-79:1).

Equally telling on the issue of reliability is Dr. McKinney's failure to subject any of his "personal experience" conclusions to peer review. Courts have excluded expert testimony where "instead of using many examples to arrive at a singular conclusion, [the expert] is attempting to rely solely on his own personal experience". *Trevino v. City of Rock Island Police Dep't*, 91 F. Supp. 2d 1204, 1206-1207 (C.D. Ill. 2000). See also *Daubert v. Merrell Dow Pharms., Inc*., 43 F.3d 1311, 1319 (9th Cir. 1995) (excluding evidence based "entirely on the experts' unadorned assertions that the methodology they employed comports with standard scientific procedures" since "the expert's bald assurance of validity is not enough" to show that the method is based on "scientifically valid principles"); *Bennett v. PRC Public Sector, Inc*., 931 F. Supp. 484, 494, n. 21, and 502, n. 42 (S.D. Tex. 1996) (expert's opinion that defective design of workstation caused plaintiffs' injuries held inadmissible; among other deficiencies, expert's statement that he had "discussed [his conclusion] with my peers and I have gotten concurrence with my thoughts" did not constitute adequate "peer review" under *Daubert*).

Dr. McKinney's opinions suffer from these same defects. Despite referring to numerous "publications" and a website, Dr. McKinney admitted in his deposition that nothing he has written has been subject to peer review. (Exhibit "E" at 47:20-48:1; 121:2-4).

Even if Dr. McKinney were permitted to testify concerning his personal experiences with Prolene that he observed, his testimony provides no basis for allowing him to draw broader conclusions. *Wise v. C. R. Bard, Inc*., 2015 U.S. Dist. LEXIS 14869, *46-48 (S.D. W. Va. Feb. 7, 2015) (expert "may testify about the complications he has observed in patients implanted with

the Avaulta (without referring to complication rates), but, as I explained in *Eghnayem, et al. v. Boston Scientific Corp*., he lacks the qualifications to infer conclusions from these observations as to the etiology of complications associated with a pelvic mesh device"), citing *Eghnayem, et al. v. Boston Scientific Corp*., No. 2:13-cv-07965, 2014 U.S. Dist. LEXIS 148312, 2014 WL 5320566, at *35 (S.D. W. Va. Oct. 27, 2014).

IV. Even If "Personal Experience" Is a Permissible Basis for Expert Testimony, Dr. McKinney's Opinions Are Inadmissible Here Because They Conflict with Peer Reviewed Literature.

As detailed above, Dr. McKinney not only failed to take into account numerous medical and scientific peer reviewed publications – including FDA advisories and the authorities the FDA relied upon – his "personal experience"-based opinions are directly refuted by those studies. He cannot reconcile or explain those contradictions, rendering his testimony unreliable.

This Court has held that "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'" *Tyree, supra* at *19, citing *In re Rezulin Products Liab. Litig*., 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted).

This Court also found that "if the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.'" *Tyree, supra*, citing *Abarca v. Franklin Cnty. Water Dist*., 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." (quotations omitted)); *Rimbert v. Eli Lilly & Co*., CIV 06-0874 JCH/LFG, 2009 U.S. Dist. LEXIS 68851, 2009 WL

2208570, at *14 n.19 (D.N.M. July 21, 2009) aff'd, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").

Although an expert may disagree with another study or studies, he or she must at least be prepared to explain the basis for that disagreement. *Winebarger v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 53892, *23-24 (S.D. W. Va. Apr. 24, 2015) ("I do not doubt that [expert] reviewed contrary studies. However, his methodology may be flawed if he does not provide an adequate explanation for why he disagrees with those studies."); *Tyree, supra at* *7 ("the challenging party cited to particular portions of [expert's] deposition testimony where he was asked about specific studies contrary to his opinion and, then, dismissed them in a conclusory manner without scientific basis."); *Sanchez, supra at* *32 (expert "gives no scientific basis for disagreeing with studies that find lower rates of pain in women . . . Without further explanation for his disagreement with these studies, [expert's method is unreliable."). Cf. *Sumner v. Biomet, Inc.*, 7:08-CV-98 HL, 2010 WL 4736320 (M.D. Ga. Nov. 16, 2010) aff'd, 434 F. App'x 834 (11th Cir. 2011) ("where there is a large body of contrary epidemiological evidence, it is necessary to at least address it with evidence that is based on medically reliable and scientifically valid methodology.").

Dr. McKinney fails to even attempt to reconcile his personal, unsubstantiated opinions with the large body of conflicting, peer reviewed material. As detailed above, he failed to even consider almost all of this material, including the source material for the FDA advisories, which conflict with his opinions. In light of these methodological failures, Dr. McKinney's expert testimony should be excluded.

CONCLUSION

For the forgoing reasons, this Court should preclude Dr. McKinney from giving any expert opinions in this litigation, including, but not limited to, opinions about the Prolene mesh product design, including but not limited to the opinions that Prolene mesh is reasonably safe for its intended use, and that Prolene mesh was appropriately designed for its intended use.

Dated: April 21, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to the CM/ECF participants registered to receive service in this MDL.

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